IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., and NOVOPHARM, LTD., Counterclaim Plaintiffs, v. ABBOTT LABORATORIES, FOURNIER INDUSTRIE ET SANTÉ, and LABORATOIRES FOURNIER S.A., Counterclaim Defendants.	REDACTED VERSION C.A. No. 02-1512 (SLR) CONSOLIDATED
IMPAX LABORATORIES, INC., Counterclaim Plaintiff, v. ABBOTT LABORATORIES, FOURNIER INDUSTRIE ET SANTÉ, and LABORATOIRES FOURNIER S.A., Counterclaim Defendants.	C.A. No. 03-120 (SLR) CONSOLIDATED
IN RE TRICOR DIRECT PURCHASER ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: ALL ACTIONS	C.A. No. 05-340 (SLR) CONSOLIDATED
IN RE TRICOR INDIRECT PURCHASER ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: ALL ACTIONS	C.A. No. 05-360 (SLR) CONSOLIDATED

OPENING BRIEF IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON RELEVANT MARKET DEFINITION

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

RULES & REGULATIONS

OTHER AUTHORITIES

INTRODUCTION

Plaintiffs allege that Defendants Abbott and Fournier engaged in an anticompetitive scheme to prevent the entry onto the market of generic fenofibrate by introducing new versions of its lipid-regulating fenofibrate drug TriCor and discontinuing prior versions, and by engaging in "sham" patent litigation against potential generic entrants. They allege that, by this conduct, Defendants have monopolized or attempted to monopolize the relevant market and acted in concert to restrain trade in violation of Sections 1 and 2 of the Sherman Act and various state laws. Abbott and Fournier deny all of Plaintiffs' allegations and maintain that their conduct was entirely lawful.

The narrow but entirely dispositive issue addressed in this motion is whether Plaintiffs can meet their burden of proving that Abbott and Fournier wield monopoly power in the relevant market in which TriCor competes. When the applicable law is applied to the undisputed facts, it is evident that Plaintiffs cannot, and that their claims must be dismissed as a matter of law.

Faced with the reality that TriCor holds only a small fraction of the market for lipid-regulating (or "dyslipidemia") drugs, Plaintiffs scramble to justify a narrower relevant market that might breathe life into their antitrust claims. To try to ensure a finding of monopoly power, Plaintiffs "gerrymander" market definition by alleging a variety of relevant markets, each one suited to a particular Plaintiff's objective, but none extending beyond fenofibrate products.

Undisputed, empirical evidence contradicts Plaintiffs' narrow proposed markets and renders their claims subject to dismissal as a matter of law. Specifically, REDACTED

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These data indisputably demonstrate that TriCor and other dyslipidemia drugs are considered reasonably interchangeable by physicians – who are the "customers" in this industry – and that TriCor does not have monopoly power in the relevant market in which these drugs compete.

Plaintiffs can raise no genuine issue of material fact to the contrary. Indeed, *the only empirical evidence Plaintiffs present confirms that Defendants lack monopoly power*. REDACTED

This is insufficient as a matter of law to convey monopoly power. In the face of this data, Plaintiffs argue that cross-price elasticity should be the measure of the relevant market, but their approach ignores the primary means of competition in the prescription drug industry and leads to implausible and absurd results. Plaintiffs' relevant market allegations thus fail and summary judgment must be granted.

BACKGROUND

Dyslipidemia is a condition characterized by the presence of abnormal lipoprotein and/or triglyceride levels in the blood. Cholesterol and triglycerides are processed through the liver, resulting in the production of very low density lipoproteins ("VLDL") and high density lipoproteins ("HDL"). VLDL is broken down into a smaller lipoprotein, called low density lipoprotein ("LDL"). Because elevated levels of LDL are associated with atherosclerosis, which can result in heart attacks and strokes, LDL is often referred to as "bad cholesterol." HDL, on the other hand, is referred to as "good cholesterol" because increased levels of HDL decreases the risk of atherosclerosis. Elevated triglycerides, which are associated with high VLDL, are

also an indicator for increased risk of atherosclerosis. Dyslipidemia presents a wide variety of characteristics in different patients, including elevated LDL, low HDL, elevated triglycerides, or various combinations of these lipids.[1] Although a physician's treatment decision will depend on a number of factors relating to the patient's overall health, their LDL, HDL, and triglyceride levels is a critical factor in the diagnosis and treatment of dyslipidemia.

The FDA has approved numerous drugs to treat patients with dyslipidemia, and the majority of dyslipidemia drugs are approved to treat all three lipids – LDL, HDL, and triglycerides.[2] Dyslipidemia drugs include HMG-CoA reductase inhibitors (called "statins"), fibrates, niacins, omega-3 fatty acids, ezetimibe, and bile acid sequestrants.[3] Within each class of drugs are various molecules. The statin class includes Lipitor (atorvastatin), Zocor (simvastatin), Pravachol (pravastatin), Crestor (rosuvastatin), Lescol (fluvastatin), and Mevacor (lovastatin), and the fibrate class includes fenofibrates (TriCor and others) and gemfibrozil.[4] Niacin is available over the counter or in the extended release prescription form Niaspan.[5] Physicians can prescribe one lipid altering drug ("monotherapy"), or two or more in combination ("polytherapy").[6] In addition, in recent years several "single pill" combination products, like Vytorin (combination of simvastatin and ezetimibe approved in July 2004), have also entered the market.

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[1] *See generally* Expert Report of Dr. Peter Jones ("P. Jones Rpt."), ¶¶ 9-12, DJA-850-51; *see also* Expert Report of Dr. Sander Robins ("Robins Rpt."), 5-6 (§ IV.A), DJA-1039-40.

[2] P. Jones Rpt., ¶ 17, DJA-853.

[3] *Id.*; Robins Rpt., 6-8, DJA-1040-42.

[4] P. Jones Rpt., ¶ 17, DJA-853.

[5] Robins Rpt., 8, DJA-1042.

[6] P. Jones Rpt., ¶ 19, DJA-854.

UNDISPUTED FACTS

1. The physician, not the patient/end-user of the product, is the primary decision maker when it comes to deciding which drug to prescribe. In making prescribing decisions, a physician's main concern is safety and therapeutic efficacy, not cost. (Section II).

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3. Physicians make prescribing decisions for their dyslipidemia patients by assessing a wide variety of factors, with emphasis on the patients' lipid profiles. (Section II.B).

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5. The dyslipidemia market is dominated by statins which constitute approximately 80% of all prescriptions to treat dyslipidemia. (Sections II.A).

6. TriCor is indicated in its FDA-approved product label to reduce LDL and triglycerides and to increase HDL. No fewer than nine other non-fenofibrate drugs in the

dyslipidemia market – including Lipitor, Zocor, Pravachol, and Crestor (all statins), Niaspan (a niacin), Advicor (a niacin/statin combination drug), and Lopid (gemfibrozil) – share TriCor's indications for the treatment of all three lipid levels. Four remaining non-fenofibrate branded drugs – Lovaza, Mevacor, Welchol, and Zetia – share indications with TriCor for the treatment of at least one lipid abnormality. (Section II.A.1).

7. Fenofibrate is not singled out as the only viable treatment for any particular lipid condition by the leading clinical guidelines for cholesterol testing and management. (Section II.A.2).

8. TriCor's initial pricing and subsequent price increases were in line with other branded drugs in the dyslipidemia market. (Section II.B.2).

9. It is rare for a branded drug to compete on price with its AB-rated generic because physicians or patients who would prefer a brand drug in a "but for" world in which there is an AB-rated generic on the market are the least price sensitive purchasers. (Section III.B.1) REDACTED

(Section III.B.1.)

10. Sales of fenofibrate would have been no greater in the "but for" world where AB-rated generics entered the market than they were in the actual world. (Section IV.C.1).

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(Section IV.C.2).

ARGUMENT

I. SUMMARY JUDGMENT IS APPROPRIATE WHERE, AS HERE, THE DEFENDANTS LACK MONOPOLY POWER IN THE RELEVANT MARKET

Where "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact . . . the movant is entitled to judgment

as a matter of law." Fed. R. Civ. P. 56 (c). *See Celotex Corp. v. Catrette*, 477 U.S. 317, 323 (1986). To avoid summary judgment, a plaintiff must be able to show evidence that is more than merely colorable; there must be enough evidence to enable a jury reasonably to find for the nonmoving party on that issue. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249-50 (1986); *Cheminor Drugs Ltd. v. Ethyl Corp.*, 168 F.3d 119 (3d Cir. 1999).

"Liability under § 2 [of the Sherman Act] requires: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen or historic accident." *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 306-07 (3rd Cir. 2007) (quotation and citation omitted). There is no presumption of market power in a patented product. *Ill. Tool Works, Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 43 (2006). Thus, an assessment of monopoly power must be based on "the structure and composition of the relevant market." *Broadcom Corp.* 501 F.3d at 307.[7]

[7] Defendants use the term "monopoly power" throughout this brief, but the analysis is equally applicable to all of Plaintiffs' claims under Sherman Act Sections 1 and 2. Plaintiffs must show the requisite market power or monopoly power – terms that are used interchangeably by some courts – in a properly defined relevant market to support their monopolization, attempted monopolization, and conspiracy to monopolize claims under Section 2, and their claims under Section 1. *See Gordon v. Lewistown Hosp.*, 423 F.3d 184, 212 (3d Cir. 2005) (The court must "determine whether the [defendant] possessed market power in the relevant markets in order to determine if we may presume anticompetitive effects from the [alleged restraint] under the [Sherman Act § 1] rule of reason test. . . . Once the markets are defined, we must determine whether the [defendant's] market share is sufficient to infer the existence of market power."); *Pastore v. Bell Tel. Co.*, 24 F.3d 508, 512 (3d Cir. 1994) (applying test in attempted monopolization claim); *Globespanvirata, Inc. v. Texas Instruments, Inc.*, No. 03-2854 (GEB), 2006 WL 543155, at *3 (D.N.J. Mar. 3, 2006) (same, as to attempted monopolization or conspiracy to monopolize claims); *Urdinaran v. Aarons*, 115 F. Supp. 2d 484, 491 (D.N.J. 2000). Moreover, as Indirect Purchaser Class Plaintiffs have admitted, Plaintiffs' state antitrust law claims generally follow federal precedent. Br. In Supp. of Indirect Purchaser Pls.' Mot. For Class Certification (C.A. No. 05-360, D.I. 117) at 23 (citing cases); *see also, e.g., Golan v. Pingel Enter.*, 310 F.3d 1360, 1369 (Fed. Cir. 2002) ("Sherman Act decisions are applicable to cases under the Cartwright Act."); *Eon Labs., Inc. v. SmithKline Beecham Corp.*, 298 F. Supp. 2d 175, 183 (D. Mass. 2003) (recognizing role of federal antitrust law in interpreting Arizona's state

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The relevant antitrust market inquiry has two elements: (1) a relevant product market, and (2) a relevant geographic market. *Brown Shoe Co. v. United States*, 370 U.S. 294, 324 (1962). Plaintiffs bear the burden of proof as to both aspects. *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 436-38 (3d Cir. 1997) (citation omitted).[8] Where plaintiffs fail to present sufficient evidence in support of their proffered market definition or where the undisputed facts support the definition of a different market, summary judgment is appropriate. *E.g., Ideal Dairy Farms, Inc. v. John Labatt, Ltd.*, 90 F.3d 737, 749 (3d Cir. 1996) (upholding grant of summary judgment where plaintiff "failed to clearly establish the relevant product and geographic market necessary to make [its actual monopolization] claim.").

II. UNDISPUTED FACTS DEMONSTRATE THAT, AS A MATTER OF LAW, THE RELEVANT MARKET INCLUDES A RANGE OF DYSLIPIDEMIA DRUGS

Plaintiffs in this action all propose narrow relevant markets that are essentially limited to TriCor and its generic equivalents, though they cannot agree on the specific parameters of the market. Some specify a relevant market that includes only TriCor and its putative AB-rated generic equivalents,[9] while others proffer variations on a market that would encompass all

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antitrust laws). Finally, dismissal of Plaintiffs' antitrust claims also would warrant dismissal of Plaintiffs' unjust enrichment claims. *See, e.g., Servicetrends, Inc. v. Siemens Med. Sys., Inc.*, 870 F. Supp. 1042, 1076 (N.D. Ga. 1994) (dismissing unjust enrichment claim as "without foundation" upon dismissal of underlying antitrust claims); *Kramer v. Pollock-Krasner Found.*, 890 F. Supp. 250, 257 (S.D.N.Y. 1995) (dismissing unjust enrichment claim predicated on dismissed antitrust claims).

[8] In this case, Plaintiffs allege a relevant geographic market that is limited to the United States. Defendants do not dispute the geographic parameters of Plaintiffs' proffered market. However, Plaintiffs' allegations as to the relevant *product* market are not supported by the evidence.

[9] Consolidated Direct Purchasers' economist expert Stephen Schondelmeyer defines the market as REDACTED Expert Report of Dr. Stephen Schondelmeyer ("Schondelmeyer Rpt."), ¶ 14.c, DJA-828. Pacificare alleges a similar market in its Complaint, Pacificare First Am. Compl. (C.A. No. 05-360, D.I. 35) ¶ 17, but its only economic expert, Hal Singer, REDACTED

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bioequivalent fenofibrate products, including any "branded generics."[10] But each of Plaintiffs' contrived markets fail because the clear and undisputed evidence shows that TriCor competes vigorously with other non-fenofibrate dyslipidemia drugs in every therapeutic category in which it is prescribed. TriCor is neither the only choice, nor the dominant player, in the treatment of any form of dyslipidemia.

It is well-established that the relevant market is comprised of all products "reasonably interchangeable by consumers for the same purposes . . . ." *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 395 (1956); *Broadcom Corp.*, 501 F.3d at 307 ("Competing products are in the same market if they are readily substitutable for one another; a market's outer

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Deposition of Dr. Hal Singer ("Singer Dep."), 29:6-9, DJA-151. Pacificare cannot meet its burden of proof as to the relevant market.

[10] The Manufacturer Plaintiffs, Teva and Impax, both allege this slightly broader "fenofibrate molecule" market definition because it would encompass the products they currently sell. Teva Second Am. Countercl. (C.A. No. 02-1512, D.I. 369) ¶ 228-232, 236; Impax Second Am. Countercl. (C.A. No. 03-120, D.I. 356) ¶ 133. But as discussed in detail *infra*, these Plaintiffs rely almost exclusively on REDACTED *See, e.g.,* Rebuttal Expert Report of Dr. Iain Cockburn ("Cockburn Rebuttal"), ¶¶ 50-87, DJA-1072-86; *see also* Teva's Answering Brief In Opp'n to Abbott and Fournier's Mot. to Dismiss Countercl. (C.A. No. 03-120, D.I. 313) at 5 RED ACT ED Thus, these Plaintiffs' own market definition theories do not support the relevant markets they propose.

One of Consolidated Direct Purchasers' experts – Jeffrey Leitzinger – proposes a market that includes REDACTED Expert Report of Dr. Jeffery Leitzinger ("Leitzinger Rpt."), 56, DJA-765. His position thus differs from that of their other expert, Schondelmeyer. *See* note 10. Opt-out Direct Purchaser Plaintiffs CVS, Rite Aid, and Walgreens allege that the relevant product market is the REDACTED CVS Pharmacy and Rite Aid Class Am. Compl. (C.A. No. 05-340, D.I. 31) ¶ 112, Walgreen Am. Compl. (C.A. No. 05-340, D.I. 30) ¶ 120, but their expert Keith Leffler has conceded that the relevant product market could be REDACT Deposition of Dr. Keith Leffler ("Leffler Dep."), 44:16, DJA-62. These inconsistencies alone suggest that Plaintiffs have failed to properly define the market. *See Home Health Specialists, Inc. v. Liberty Health Sys.*, No. 92-3413, 1994 WL 463406, at *5, *aff'd* 65 F.3d. 162 (3d Cir. 1995) (noting that plaintiff's shifting claims of relevant market provide "more evidence the Plaintiff has not established . . . the relevant geographic market.").

boundaries are determined by the reasonable interchangeability of use between a product and its substitute, or by their cross-elasticity of demand." (citing *Brown Shoe*, 370 U.S. at 325). In determining the bounds of a relevant market or submarket, "the emphasis is on the actual dynamics of the market, rather than the rote application of any formula." *Geneva Pharm. Tech. Corp. v. Barr Labs Inc.*, 386 F.3d 485, 496 (2d Cir. 2004). As a result, courts use many different kinds of evidence to determine which products are reasonably interchangeable, including customer views on the interchangeability of the products, the relationship between the price of one product and the sales of another, industry or public perception of separate markets or submarkets, and the view of firms regarding who their competitors are.[11]

In the pharmaceutical industry, the most vigorous head-to-head competition for prescription drug sales occurs in the battle for prescriptions. It is the physician, not the patient/end-user of the product, who is the primary decision maker regarding which drug to prescribe.[12] And because physicians' main concern is safety and therapeutic efficacy, not cost,[13]

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[11] ABA SECTION OF ANTITRUST LAW, ANTITRUST LAW DEVELOPMENTS at 558-61 (6th ed. 2007), *reprinted in* 1-6 Antitrust Law Developments 6B (LEXIS) (citing cases).

[12] Expert Report of Dr. Richard Gilbert ("Gilbert Rpt."), ¶ 21, DJA-960-61 REDACTED

Schondelmeyer Rpt., ¶ 159, DJA-829 REDACTED

¶ 33, DJA-785 REDACTED

; Deposition of Dr. Jeffrrey Leitzinger ("Leitzinger Dep."), 50:16-18, DJA-204 REDACTED

Cockburn Rebuttal, ¶ 68, DJA-1080 (R REDACTED

Surrebuttal Report of Charles King III Concerning Liability and Product Market Definition ("King Liab. Rebuttal"), ¶ 36, DJA-1064.

[13] The parties' experts agree that REDACTED Gilbert Rpt., ¶ 22, DJA-960-61; Leitzinger Dep., 42:23-43:3, DJA-202; Leffler Dep., 112:1-3, DJA-72; Deposition of Charles King III ("King Dep."), 121:2-5, DJA-133; Deposition of Dr. Stephen Schondelmeyer ("Schondelmeyer Dep."), 153:2-3, DJA-117; Schondelmeyer Rpt., ¶ 160, DJA-829; Cockburn Rebuttal, ¶¶ 48-49, DJA-1071. The Courts also have recognized this

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most competition for prescriptions among drug manufacturers takes place in non-price dimensions such as research and development, product improvements, product differentiation, and, importantly, marketing to physicians to persuade them to prescribe a particular drug. The Manufacturer Plaintiffs' expert, Dr. Cockburn, concedes that

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An attempt to define a relevant market based on price competition would ignore the primary means of competition in this industry. Instead, the best evidence by which to determine the bounds of the relevant market is evidence of physicians' behavior, *i.e.*, *what physicians actually prescribe when faced with a particular medical condition*.[15]

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unique characteristic of the pharmaceutical industry. *See, e.g.*, *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1063 (3d Cir. 1978) ("Prescribing physicians are not cost-conscious in their choices of an antibiotic for a hospitalized patient, and so do not opt for a less expensive over a more costly medication."); *In re Brand Name Prescription Drugs Antitrust Litig.*, 288 F.3d 1028, 1030 (7th Cir. 2002) ("[P]hysicians are often indifferent to the price of the drug they are prescribing."); *United States v. Ciba Geigy, Corp.*, 508 F. Supp. 1118, 1153 (D.N.J. 1976) ("When the physician prescribes, he is casting his drug decision in terms of therapeutic efficiency and not in terms of price if indeed he is aware of price variations among identical drugs. . . .").

[14] Deposition of Dr. Iain Cockburn ("Cockburn Dep."), 49:2-15, DJA-102. Dr. Cockburn RE DA CT . *Id*. at 51:5-11, DJA-103.

[15] *See Barr Labs., Inc. v. Abbott Labs*, 978 F.2d 98, 115-16 (3d Cir. 1992) (upholding district court's instructions to the jury that (1) the prescribing physician is the one who "selects the particular product in the first instance . . . . [Y]ou should thus include in the relevant product market those . . . drugs which are reasonably interchangeable, price, use and qualities considered, in meeting the antibiotic needs of the patients" and (2) generic options that could be used to fill the physicians' choice of prescription drug should also be included.); *cf. Nobody In Particular Presents, Inc. v. Clear Channel Comm'ns. Inc.*, 311 F. Supp. 2d 1048, 1076 (D. Colo. 2004)
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A. Undisputed Empirical Evidence Demonstrates that Doctors Use a Broad Range of Dyslipidemia Drugs Interchangeably with TriCor

To assess the parameters of the competition TriCor faces, Defendants' expert Dr. Richard Gilbert conducted an analysis of the *actual options considered and prescribed by physicians* when treating patients with dyslipidemia. His analysis demonstrates unequivocally that RED ACTE D

Dr. Gilbert analyzed REDACTE D

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("[T]he identity of the relevant customer for the purposes of determining market definition is not necessarily the end-user of the product . . . .").

[16] Dr. Gilbert analyzed REDACTED

Rpt., ¶ 40, DJA-1017.

[17] Gilbert Rpt., ¶ 42, DJA-1017-18. The NCEP and the American Diabetes Association ("ADA"), regularly issue evidence-based clinical guidelines for cholesterol testing and management to physicians. *See, e.g.*, Executive Summary, Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III), NIH Publication No. 01-3670 (May 2001) [hereinafter "ATP III Executive Summary"], DJA-1169-1208; Standards of Medical Care in Diabetes - 2007, *Diabetes Care*, Volume 30, Supp. (January 2007) [hereinafter "ADA Guidelines"], DJA-1388-1477.

[18] Gilbert Rpt., ¶ 43, DJA-1019; Supplemental Expert Report of Dr. Richard Gilbert ("Gilbert Supp"), ¶ 7, DJA-1109.

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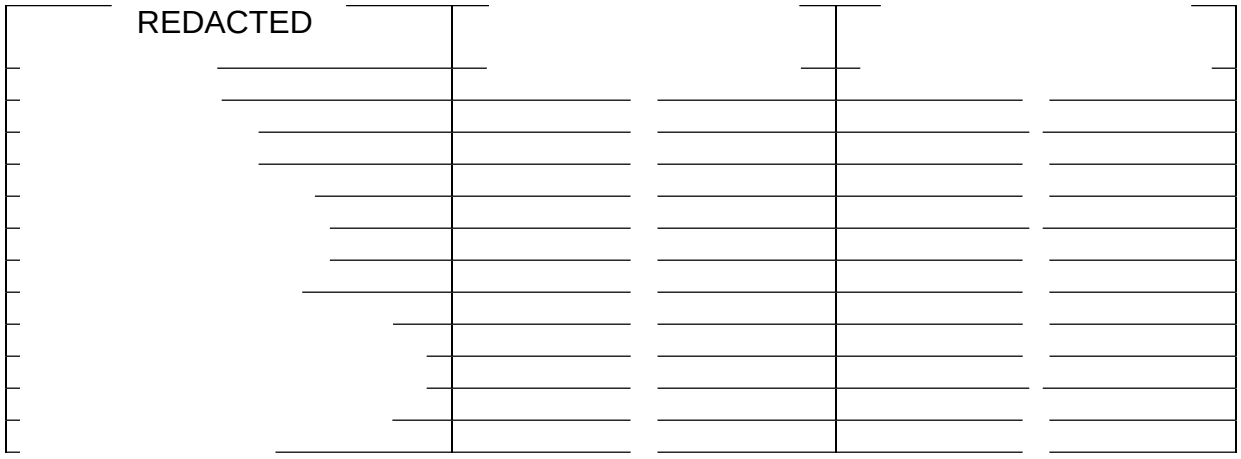

Plaintiffs present no empirical analysis to dispute Dr. Gilbert's findings.[19] Instead, Plaintiffs' economic experts focus on Abbott marketing documents describing attempts by

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[19] As discussed *infra*, only one of Plaintiffs' experts – Dr. Cockburn – presents any empirical analysis at all, and his effort only further demonstrates Defendants' lack of monopoly power.

[20] *See* Leffler Rpt., ¶ 39, DJA-787-88; Schondelmeyer Rpt., ¶ 177, DJA-832; Declaration of Charles King III Concerning Liability and Product Market Definition ("King Liab. Decl."), ¶ 26, DJA-800; Expert Report of Dr. Iain Cockburn ("Cockburn Rpt."), ¶ 105, DJA-712.

[21] REDACTED . Expert Report of Dr. Richard Grimm ("Grimm Rpt."), 11, DJA-744 REDACTED 57, DJA-844-45;

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.[22] Plaintiffs' experts go on to charge that REDACTED

.[23]

The empirical data presented by Dr. Gilbert – and unrefuted by Plaintiffs – is conclusive and flatly contradicts Plaintiffs' claims. For example, "mixed" dyslipidemia is characterized by high levels of triglycerides in combination with low levels of HDL. REDACTED

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Schondelmeyer Rpt., ¶ 177, DJA-832; Leffler Rpt., ¶ 32, DJA-784-85; Cockburn Rebuttal, ¶ 61.3, DJA-1076-77 REDACTED

[22] Cockburn Rpt., ¶ 105, DJA-712; Schondelmeyer Rpt., ¶ 177, DJA-832; Leffler Rpt., ¶ 39, DJA-787-88; *but see* Leffler Rpt., ¶ 32, DJA-784-85 REDACTED

King Liab. Decl., ¶ 26, DJA-800.

[23] Cockburn Rpt., ¶¶ 108-24, DJA-713-18 REDACTED
REDACTED Schondelmeyer Rpt., ¶¶ 172-77, DJA-832 REDACTED
Leffler Rpt., ¶ 39, DJA-787 REDACTED
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[24] Gilbert Supp., Table 1b, DJA-1113.

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and conclusive evidence that these drugs are interchangeable from a market perspective.

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1. The Results of the Empirical Data Comport with the Undisputed Evidence that No Fewer than Nine Other Dyslipidemia Drugs Share TriCor's Indications for Lowering TGs, Lowering LDL-C and Raising HDL-C

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is not surprising in light of the FDA-approved labels for these drugs. A drug's product label, which is also referred to as the "package insert" is an FDA mandated and regulated document that contains important information such as a description of the drug product, its clinical pharmacology, indications and use, contraindications, warnings, and dosage and administration. For an indication to be included on a product's label, the claimed use "must be supported by substantial evidence of effectiveness based on adequate and well-controlled studies," 21 C.F.R. § 201.57(c)(2)(iv) (2007), meaning that the drug manufacturer

[25] *Id.* at Table 2b, DJA-1114. As discussed further *infra*, increasing the dosage of a statin molecule – rather than the addition of a second drug – is an alternative to adjunctive therapy outlined in the ATP III Guidelines. REDACTED Gilbert Rpt., ¶ 51, DJA-1022.

must prove to the FDA's satisfaction that the drug product is effective at treating the indicated condition. The label controls what information a pharmaceutical company is permitted to disseminate in marketing efforts, 21 C.F.R. § 203.1(d)(3)(iii)(4) (2007), and also appears in the Physician's Desk Reference ("PDR"), an important source of information for physicians.

TriCor is indicated in its FDA-approved product label to reduce LDL and triglycerides, and to increase HDL.[26] No fewer than nine other non-fenofibrate drugs in the dyslipidemia market share TriCor's indications for the treatment of all three lipid levels. Each of the four remaining non-fenofibrate branded drugs – Lovaza, Mevacor, Welchol, and Zetia – share indications with TriCor for the treatment of at least one lipid abnormality:[27]

LIPID DRUGS	**INDICATIONS**		
	Lower LDL	**Lower TG**	**Increase HDL**
TriCor (fenofibrate)	**X**	**X**	**X**
Advicor (niacin/statin)	X	X	X
Crestor (statin)	X	X	X
Lescol (statin)	X	X	X
Lipitor (statin)	X	X	X
Lopid (gemfibrozil)	X	X	X
Niaspan (niacin)	X	X	X
Pravachol (statin)	X	X	X
Vytorin (ezetimibe/statin)	X	X	X
Zocor (statin)	X	X	X
Lovaza (omega-3 fatty acid)		X	
Mevacor (statin)	X		
Welchol (bile acid sequestrant)	X		
Zetia (ezetimibe)	X		X

[26] TriCor 48 mg and 145 mg product label, DJA-1387.001-1387.012 (TriCor indicated "to reduce elevated LDL-C, Total-C, Triglycerides and Apo B, and to increase HDL-C in adult patients with primary hypercholesterolemia or mixed dyslipidemia," as well as "for treatment of adult patients with hypertriglyceridemia.").

[27] Like TriCor, Lipitor, Zocor, Pravachol, Crestor, Niaspan, Advicor, and Lopid, all are specifically approved to treat hypercholesterolemia, mixed dyslipidemia and hypertriglyceridemia. Physicians' Desk Reference, 672-75, 943-48, 1694-99, 1703-07, 2078-84, 2495-98 (60th ed. 2006) [hereinafter "60th ed. PDR"], DJA-1337-40, 1341-46, 1347-52, 1353-57, 1358-64, 1377-80; Physicians' Desk Reference 2650-53 (56th ed. 2002), DJA-1211-12; Lovaza, formerly known as Omacor, is indicated, and interchangeable with TriCor, for the reduction of very high triglyceride levels. 60th ed. PDR, *supra* note 27, at 2735-36, DJA-1386-87.

2. Undisputed Evidence Concerning Leading Cholesterol Treatment Guidelines Further Confirms That TriCor Competes with other Dyslipidemia Drugs

The leading cholesterol treatment guidelines also are consistent with Dr. Gilbert's finding

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[28] The ATP III Guidelines, and the Standards of Medical Care in Diabetes promulgated by the ADA, recommend a number of alternative drug therapies for the treatment of hypercholesterolemia, mixed dyslipidemia, and hypertriglycerdemia.

Nowhere in the ATP III or ADA Guidelines is TriCor, or fenofibrate, singled out as the only viable treatment (or even the most preferred treatment) for a particular lipid condition. For example, the Guidelines counsel that in patients with high serum triglycerides, non-HDL cholesterol becomes a secondary target of treatment to reducing LDL-C, [29] and treatment options include "intensifying therapy with an LDL-lowering drug" (because most such drugs will also have beneficial effects on the elevated triglycerides) or the addition of "nicotinic acid or fibrate."[30] "Intensification" of LDL-lowering therapy would mean increasing the dose of a statin or other drug already prescribed to the patient or, less frequently, adding a second statin.[31] Thus, consistent with the Guidelines, prescribing options for patients with this form of mixed dyslipidemia include:

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[28] Plaintiffs' physician experts agree REDACTED . *See, e.g.*, Schwartzbard Dep., 360:5-10, DJA-146; Soto Dep., 77:2-8, 202:3-20, DJA-175, 196; Robins Rpt., 9-10, DJA-1043-44; Grimm Rpt., 9, DJA-742; Robins Dep., 162:6-11, DJA-91; Soto Dep., 79:15-21, DJA-176 REDACTED .

[29] "Non-HDL cholesterol" is defined as the sum of LDL + VLDL. ATP III Executive Summary, *supra* note 17, at 18, DJA-1196. REDACTED P. Jones Rpt, ¶10, DJA-850-51.

[30] ATP III Executive Summary, *supra* note 17, at 19, DJA-1197.

[31] Robins Dep., 150:16-152-13, DJA-88.

1) monotherapy with a statin (with an increase in dose to address triglycerides and HDL)
2) monotherapy with another LDL-lowering drug
2) polytherapy with a statin and a fibrate, or
3) polytherapy with a statin and nicotinic acid.32

In other words, under the Guidelines, a physician treating these patients can either ***prescribe more statin*** or other LDL-lowering drug, ***or prescribe either fenofibrate, gemfibrozil or niacin.*** Similar treatment options exist under the Guidelines for other mixed dyslipidemia patients.

In addition to the ATP III and ADA Guidelines, other reference works advise that statin therapy is adequate even when triglycerides are elevated. For example, a physician consulting the Washington Manual of Medical Therapeutics ("Washington Manual")[33] would learn that patients with hypertriglyceridemia whose triglycerides are less than 400 mg/dL "may respond adequately to a statin added to nonpharmacologic measures," and that fenofibrate is only one of a number of options for patients whose triglycerides are above 400 mg/dL.[34] The Manual also recommends niacin over fibrates as a second drug to a statin in combination therapy.[35]

Plaintiffs will undoubtedly try to point to testimony by other physician experts to the effect REDACTED

[32] ATP III Executive Summary, *supra* note 17, at 9, DJA-1187; Robins Dep., 221:2-222:2, DJA-96-97. No distinction is made between "fibrates" in these alternative treatment options. *See also* Robins Dep., 212:1-10, DJA-94 REDACTED

id. at 210:23-211:4, DJA-94 REDACTED

[33] Deposition of Dr. Richard Grimm ("Grimm Dep."), 334:14-335:14, DJA-165 (Physicians "will refer to their Washington Manual all the time." "[U]sually physicians would carry this little book in their pocket and whenever it came to, okay, I need to prescribe this drug, and they are not all that familiar with the drugs, so they will look it up in this manual and it will tell them the dose of the drug to use.").

[34] Daniel H. Cooper, M.D. (ed.), et. al, *Washington Manual of Medical Therapeutics* 164 (32nd ed. 2007), DJA-1487, (noting that treatment for these patients "could include a statin at higher doses, gemfibrozil, fenofibrate, niacin, or omega-3 fatty acids."). The Manual also notes that statins may lower triglycerides by up to 30%. *Id*. at 162, DJA-1485.

[35] Id.

REDACTED But the prescribing practices of one or several litigation "experts" do not raise an issue of material fact when real world data reflecting actual prescriptions written by physicians in the marketplace support REDACTED [36]

In any case, the testimony of Plaintiffs' experts highlights that physicians can and do choose other dyslipidemia drugs over TriCor even where TriCor might theoretically be a better therapeutic option. REDACTED

[7] Dr. Grimm, the physician expert for the Indirect Purchasers, REDACTED

For treatment of elevated triglycerides, for instance, R E D [38] REDACTED .[39] There is perhaps no better evidence that TriCor continues to face competition in the marketplace from other dyslipidemia drugs than REDAC TED

Thus, while Plaintiffs' experts offer many different opinions regarding which dyslipidemia drug might *optimally* be used in various treatment circumstances, what the

[36] *See Advo v. Philadelphia Newspapers, Inc.*, 51 F.3d 1191, 1198-99 (3d Cir. 1995) (opinion expert testimony without a factual foundation cannot defeat a motion for summary judgment); *Virgin Atl. Airways, Ltd. v. British Airways PLC*, 69 F. Supp. 2d 571, 578 (S.D.N.Y. 1999) (summary judgment granted where antitrust plaintiff's expert's opinion was based on assumptions not supported by market data). *See also Exxon Corp. v. Koutney*, 51 Cal. App. 4th 1672, 1683 (1997) (noting that the speculative opinions of plaintiff's expert Keith Leffler "do not rise to the status of contradictory evidence.").

[37] Soto Dep., 151:17-23, 152:23-155:4, DJA-186.

[38] Grimm Dep., 82:25-83:6, DJA-161.

[39] *Id.* at 81:21-82:24, DJA-160-61.

empirical data show, and what FDA-approved indications, treatment guidelines, and testimony from Plaintiffs' own experts make clear, is that as a practical matter these dyslipidemia drugs are interchangeable, from a market perspective, in all patient categories.[40]

3. Plaintiffs Can Raise No Issue of Fact to Dispute the Results of Dr. Gilbert's Analysis

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Despite the availability of REDACTED, none of Plaintiffs' experts presented any competing contrary analysis of that data.[41] Instead, unable to explain away Dr. Gilbert's results, Plaintiffs' experts REDACTED .[42] But

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REDACTED This further underscores the limitations on "expert" evidence proffered by cardiology specialists, and the need instead to examine broad-based empirical prescription data in any assessment of the relevant market, as Dr. Gilbert has done here.

[41] REDACTED ¶¶ 72-76, DJA-1081-84, REDACTED *See* Leffler Dep., 43:1-4, DJA-62 REDACTED

[42] *See, e.g.,* King Liab. Rebuttal, ¶¶ 35-37, DJA-1063-65; *see also* Rebuttal Expert Report of Dr. Keith Leffler ("Leffler Rebuttal"), ¶¶ 13-15, DJA-1100-03 REDACTED Leitzinger Rebuttal, 33, at DJA-1092 REDACTED In other litigation, Dr. Leitzinger found that a branded drug competes in a relevant market with other branded drugs. REDACTED

(Continued . . .)

these responses ignore the unique qualities of the pharmaceutical industry and the lack of price sensitivity among consumer physicians, which render an entirely price-driven market definition untenable.

The Supreme Court has held that neither differences in prices nor price elasticity are determinative in setting the bounds of the relevant market. *United States v. Continental Can Co.*, 378 U.S. 441, 455 (1964) ("That there are price differentials between the two products or that the demand for one is not particularly or immediately responsive to changes in the price of the other are relevant matters but not determinative of the product market issue."). Where the circumstances of a particular market render cross-price elasticity analyses difficult to assess, courts will rely on more reliable measures of interchangeability such as the uses and qualities of the products at issue.[43] Some Plaintiffs' experts acknowledge that REDACTED

Others opine that REDACTED

(. . . continued)

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Leitzinger Dep., 58:19-60:14, DJA-206.

[43] *See Geneva Pharms.*, 386 F.3d at 496 ("The emphasis [in determining the bounds of the relevant market] is on the actual dynamics of the market rather than [the] rote application of any formula."); *see e.g., Nobody In Particular Presents*, 311 F. Supp. 2d at 1082 (holding that plaintiff could prove relevant market without cross-elasticity study where "calculations of cross-elasticity of demand are difficult when analyzing the . . . industry."). The Third Circuit underscored that a cross-price elasticity analysis is not determinative in *SmithKline Corp. v. Eli Lilly & Co.,* 575 F.2d at 1063-64, where it applied both a cross-price elasticity test *and* an interchangeability test before determining the boundaries of the relevant market. Of course, the specific facts of that case are distinguishable, because unlike in *SmithKline*, the undisputed empirical evidence here demonstrates that physicians can and do substitute a number of other dyslipidemia molecules for fenofibrate in their treatment of patients.

[44] King Liab. Decl., ¶¶ 86, 87, DJA-811-12 REDACTED
Leffler Rpt., ¶ 32, DJA-784 REDACTED

REDACTED .[45] Either way, the experts' attention to these issues serves as an acknowledgement that therapeutic substitution is an appropriate test.[46] Under the circumstances here, it is precisely such substitution that must define the parameters of the relevant market.

B. Undisputed Evidence of Abbott's Market Behavior Also Demonstrates that REDACTED

Dr. Gilbert's empirical analysis showing that TriCor is in a market with all dyslipidemia drugs is reinforced by the market behavior of both Abbott and other dyslipidemia drug manufacturers. When Abbott first received FDA approval for TriCor, the dyslipidemia market was entirely dominated by statins.[47] Although fibrates (then clofibrate and gemfibrozil) had been the most commonly prescribed anti-dyslipidemic in the 1980s, they were surpassed and thoroughly dominated by statins through the 1990s, REDACTED

[48] Statins, meanwhile, had become so well-established that they were the second most commonly prescribed class of drug in the United States.[49] RED ACTE D

[45] *See, e.g.,* Cockburn Rpt., ¶¶ 108-24, DJA-713-18 REDACTED ; Schondelmeyer Rpt., ¶¶ 172-76, DJA-830-31 REDACTED ; Leffler Rpt., ¶ 39, DJA-787-88 (REDACTED

[46] As Dr. Cockburn concedes, REDACTED Cockburn Rpt., ¶ 104, DJA-711-12.

[47] *See Id.*, ¶ 85, DJA-702-03; *see also* Leitzinger Rpt., 19, DJA-752.

[48] Cockburn Rpt., ¶ 85, DJA-702-03.

[49] Katherine Friedman, *Business Watch,* MED. MARKETING & MEDIA, May 31, 2000, at 42, DJA-1160.

[50] Expert Report of Margaret Guerin-Calvert ("Guerin-Calvert Rpt."), ¶¶ 46, 47, DJA-996-97.

REDACTED [51] The reason for this effort is clear: TriCor faced vigorous competition from statins and other already available dyslipidemia drugs.

1. The Battle to Move Physicians to a TriCor Patient Type

To gain a foothold in the dyslipidemia market, TriCor had to convince physicians accustomed to prescribing statins to prescribe TriCor instead.[52] As Plaintiffs' experts concede,

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Most patients have a combination of lipid abnormalities, and many dyslipidemia drugs are indicated to treat all or most dyslipidemic conditions. Abbott has to convince physicians that patients will benefit more from TriCor (which is now indicated to treat abnormalities in all three lipids) than from other dyslipidemia drugs (which do the same). Teva's physician expert Dr. Sander Robins has described the view of some in the medical community that REDACTED .[54] REDACTED [55] and in this case, their habit

[51] *See* Guerin-Calvert Rpt., ¶¶ 35, 36, DJA-994-95; M. Jones Decl., ¶ 39, DJA-679 REDACTED

[52] *See* REDACTED REDACTED , Teva-TriCor044144, DJA-413,

[53] P. Jones Rpt., ¶ 14, DJA-852 REDACTED

[54] Robins Dep., 160:3-161:2, DJA-90 REDACTED

(Continued . . .)

has been statins. It is against this entrenched position that Abbott and TriCor has been forced to compete.[56]

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(. . . continued)

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[55] Leffler Dep., 194:8-17, DJA-79 REDACTED

be delivered in a fresh and new way.").

[Ninety percent] of the almost 20,000 sales representatives in the REDACTED

For example, a REDACTED

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Second, it notes that REDACTED

[57] Abbott_TriCor00056920, at 937, 939, 940, DJA-381, 383, 384.

[58] REDACTED

Abbott_Tricor00000111-17, at 112, DJA-270.

[59] *Id.* at 113, DJA-271.

[60] *Id*.

[61] *Id.* at 111, DJA-269 REDACTED

Id. at 113, DJA-271. REDACTED

(Continued . . .)

Of course, from an economic perspective, the reason for the substitution is not important: The undisputed empirical evidence shows that TriCor faces formidable rivals in these drugs regardless of the patient profile. REDACTED

2. Competition Among Branded Pharmaceuticals Also Acts as a Constraint on TriCor's Price

As noted above, REDACTED and therefore is an inappropriate measure of the relevant market.[62] But this is not to say that there are no constraints on the prices manufacturers charge for their products.[63] REDACTED

(. . . continued)

REDACTED Abbott_Tricor00056920, at 940, 936, DJA-384, 380. That these and other competitor drugs in fact are actively marketing to the elevated TG/low HDL-cholesterol patient type is evident from the drugs' websites. Niaspan, Lovaza (Omacor), Vytorin, Lescol, Zetia, Advicor, and Lipitor all advertise their drugs as lowering triglycerides and or raising HDL.

[62] Gilbert Rpt., ¶ 11, DJA-958 REDACTED Leffler Rebuttal, ¶ 8, DJA-1098 REDACTED ; Rebuttal Report of Dr. Jeffrey Leitzinger ("Leitzinger Rebuttal"), 31, DJA-1090 (same); Cockburn Rebuttal, ¶ 49, DJA-1071 REDACTED

[63] Leitzinger Dep., 54:16-20, DJA-205 REDACTED ; Cockburn Dep., 47:25-48:4, DJA-102 REDACTED

REDACTED As Dr. Gilbert points out, REDACTED

Gilbert Report at 63, DJA-975.[64] REDACTED

.[65] Any claim by Plaintiffs that TriCor's price has not been constrained by competition from these other branded drugs is therefore without support.[66]

III. PLAINTIFFS' RELEVANT MARKET DEFINITIONS ARE IMPLAUSIBLE AND CANNOT WITHSTAND SUMMARY JUDGMENT

Plaintiffs' limitation of the relevant market to a REDACTED is implausible in light of the undisputed evidence in this case. Under these circumstances, summary judgment must be granted. *See Town Sound & Custom Tops, Inc. v. Chrysler Motors Corp.*, 959 F.2d 468, 479 (3d Cir. 1992) (upholding summary judgment where plaintiffs' narrow definition of the relevant product market made "no sense in terms of real world economics."); *see also Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574,

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[64] By way of example, a 2002 Abbott REDACTED DJA-291. REDACTED *See also* REDACTED at 016, DJA-222, (same). REDACTED at 932, DJA-376.

[65] *See* M. Jones Decl., ¶ 27, DJA-675-76 REDACTED

[66] Professor Cockburn in his report opines REDACTED Cockburn Rpt., ¶ 14.2, DJA-687, *but see* Cockburn Dep., 46:25-47:4, DJA-102 REDACTED

587 (1986) (finding that if the factual context renders respondent's claim implausible and the claim is one that makes no economic sense, summary judgment may be appropriate); *Ideal Dairy Farms*, 90 F.3d at 749.

A. Plaintiffs' Proffered Market Definitions Make No Economic Sense in Light of the Undisputed Facts in this Case

What most Plaintiffs propose as the relevant market – REDACTED

– is actually REDACTED

RED By proposing a market limited REDACTED that a consumer who already has a prescription for TriCor may purchase, Plaintiffs ignore the entire competitive process that defines a market in the context of pharmaceuticals: the battle for prescriptions.

Since launching TriCor REDACTED

[67] This investment is simply inconsistent with Plaintiffs' theory that TriCor does not compete with other branded dyslipidemia drugs: Abbott engages in these activities precisely *because of* the substitutability between TriCor and other dyslipidemia drugs.[68]

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[67] REDACTED , Abbott_Tricor00013709 at 794, DJA-278.

[68] REDACTED

See Leitzinger Rpt., 56 & n. 151, DJA-765; *see also* Teva's Answering Br. In Opp'n to Abbott and Fournier's Mot. to Dismiss Countercls. (C.A. No. 03-120, D.I. 313) at 5 REDACTED

B. Given the Lack of Price Sensitivity and Weak Price Competition in the Pharmaceutical Industry, Plaintiffs' Reliance on the Price-Driven Merger Guidelines Is Misplaced

The attempt by several of Plaintiffs' experts to rely on the Horizontal Merger Guidelines to define the relevant market also is misguided and misleading in light of the realities of the pharmaceutical market.[69] The Supreme Court has recognized that antitrust inquiries should be guided by "actual market realities" not "formalistic distinctions." *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 467 (1992); *see also Del. Health Care, Inc. v. MCD Holding Co.*, 957 F. Supp. 535, 543 (D. Del. 1997) (emphasizing evidence of "actual market reality" over a Merger Guidelines analysis to define relevant geographic market).

The Merger Guidelines "outline the present enforcement policy of the Department of Justice and the Federal Trade Commission . . . concerning horizontal acquisitions and mergers . . . ."[70] They were not developed for use in litigation where a merger is not at issue. Moreover, the Guidelines are a price-based framework and therefore cannot be used to reflect accurately the realities of competition in a non-price sensitive market. In these circumstances, they are an inappropriate tool with which to assess defendants' alleged monopoly power.

1. Plaintiffs' Price-Based Market Definition Framework is Inappropriate because Brands Do Not Generally Compete on Price with their AB-rated Generics.

Just as the market for branded pharmaceuticals is not price sensitive,[71] the parties generally agree that it REDACTED .[72]

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[69] *See* King Liab. Decl., ¶¶ 18, 34-35, 63-68, DJA-796, 804, 807-09; Leffler Rpt., ¶ 22, DJA-780-81; Schondelmeyer Rpt.,¶ 196 n.21, DJA-835.

[70] U.S. Dep't of Justice & Fed. Trade Comm'n, *Horizontal Merger Guidelines* § 0 (1992, revised 1997), *available at* http://www.usdoj.gov/atr/public/guidelines/hmg.pdf.

[71] *See supra* Section II.B.2.

This is because REDACTED world in which there is an AB-rated generic on the market REDACTED [73] REDACTED

Where, as here, price competition across brands is weak, and a brand does not compete on price with its AB-rated generics, a Merger

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(. . . continued)

[72] Schondelmeyer Dep., 126:22-23, DJA-113 REDACTED); Cockburn Dep., 32:2-3, 32:8-10, DJA-99 REDACTED ; Leffler Dep., 59:21-60:2, DJA-66 REDACTED Leitzinger Dep., 34:14-25, DJA-200 REDACTED Declaration of Charles King III Concerning Damages ("King Damages Decl."), ¶ 39, DJA-817 REDACTED

[73] Cockburn Dep., 32:19-33:1, DJA-99 REDACTED Leitzinger Dep., 109:3-8, DJA-210 REDACTED

[74] REDACTED Guerin-Calvert Rpt., ¶ 101, DJA-1003-04. REDACTED M. Jones Decl., ¶ 31, DJA-677. REDACTED *See, supra,* note 72; Cockburn Dep., 35:8-10, DJA-100 REDACTED Expert Declaration of Dr. Hal Singer ("Singer Decl."), ¶ 39, DJA-839-40 REDACTED Singer Dep., 62:22-63:3, DJA-157.

Guidelines approach to market definition like the one Plaintiffs advance here does not even support the narrow market definition that Plaintiffs propose. Instead, it yields the nonsensical result that TriCor (and TriCor alone) constitutes its own market.[75]

2. Application of the Merger Guidelines to the Facts of this Case Yields a Market Definition Which Does Not Reflect Market Reality.

A determination of the relevant product market under the Merger Guidelines begins with "each product (narrowly defined) produced or sold by each merger firm" and asks "what would happen if a hypothetical monopolist of that product imposed at least a 'small but significant and nontransitory' increase in price."[76] If the resulting reduction in sales would be sufficiently large that the price increase would prove unprofitable, then the next best substitute will be added to the relevant market.[77] Adapting this test to the context here requires that the test be phrased as

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[78] Alternatively, REDACTED

.[79]

If TriCor faced AB-rated generic competition, its price would not be constrained by the price of the AB-rated generic; it could increase or stay the same without a consequent loss of

[75] Gilbert Rpt., ¶ 75, DJA-980.
[76] *Horizontal Merger Guidelines*, supra note 70, at § 1.11.
[77] Gilbert Rpt., ¶ 75, DJA-980.
[78] *Id.* at ¶ 71, DJA-979.
[79] *Id*. at ¶ 72, DJA-979-80.

profitability. Under the Merger Guidelines, TriCor would therefore be in its own relevant market. Not surprisingly, "[e]xcept in rare circumstances, courts reject market definitions consisting of one supplier's products where other brands compete." *Town Sound & Custom Tops*, 959 F.2d at 480.[80] This unsound result highlights the lack of suitability of the Merger Guidelines to a case involving alleged monopolization of a non-price sensitive market.

C. Because Plaintiffs' Underlying Theories Lead to Absurd Results, the Market Definitions They Advance Must be Rejected As a Matter of Law

As demonstrated, applied as written, the Merger Guidelines lead to the absurd conclusion that TriCor – and likely other brand name drugs – each occupy and monopolize their own relevant markets. Adherence to the kind of strict cross-price elasticity approach proposed by the Plaintiffs would yield equally nonsensical results. Such an approach requires the conclusion that the only meaningful competition in the branded pharmaceutical market is between the branded product and its AB-rated generic, through generic substitution. Indeed, under this approach, the only "economic" substitute for the branded product is its AB-rated generic equivalent, with even

[80] This is not a mere hypothetical application of Plaintiffs' theory. Indeed, the Second Circuit has held that a branded drug does not compete, and thus is not in the same market as, its AB-rated generic counterparts primarily because there was no price competition between the AB-rated generics and the branded drug. *Geneva Pharms.*, 386 F.3d at 496-99. The allegations in that case were much different than those at bar in that the plaintiff – an AB-rated generic – claimed another AB-rated generic had entered an illegal exclusive dealing arrangement with a supplier to monopolize the market. *Id.* at 494. The branded drug manufacturer was not a party to the case, and the Court did not assess whether competition between branded products existed. Nevertheless, the Second Circuit's acknowledgement that branded drugs and their AB-rated generics do not compete on price squares with the facts of this case. *Id*. at 496-97. Of course, if branded TriCor and any potential AB-rated generics were found to compete in separate markets, Manufacturer Plaintiffs would have no standing to allege that Defendants have monopolized a "branded TriCor market." *See Barton & Pittinos, Inc. v. SmithKline Beecham Corp.*, 119 F.3d 178, 181-84 (3d Cir. 1997) (denying standing to plaintiff that was not a consumer nor a competitor of the defendant's product). Moreover, Defendants cannot monopolize a market comprised only of AB-rated generic fenofibrate because they do not compete in such a market. *Pastore*, 24 F.3d at 513 ("Without any share in the relevant market . . . , there can be no inference that defendants hold sufficient economic power in that market to create a dangerous probability of monopoly.").

branded generics and other branded fenofibrates carved out from the relevant market. But such a theory leads to the absurd conclusion that *every* brand name drug comprises a separate relevant product market and every such product is its own antitrust monopoly. This simply cannot be.

Under Plaintiffs' theory, there would be no reason for brand name pharmaceutical manufacturers to compete for sales because none of their products would be substitutes. Billions of dollars that are currently being spent by these companies to gain market share and shift sales to their products would be without purpose. Among other things, if every relevant product market in the pharmaceutical industry were defined on the basis of AB-rated bioequivalence, it would be hard to imagine how any merger between pharmaceutical manufacturers would harm competition. Courts uniformly reject plaintiffs' assertions of relevant market where the proposed markets are implausible or economically nonsensical, and the Court should reject Plaintiffs' market definitions here. *See Town Sound & Custom Tops*, 959 F.2d at 479.[81]

IV. PLAINTIFFS CANNOT MEET THEIR BURDEN OF ESTABLISHING THAT DEFENDANTS POSSESS MONOPOLY POWER IN ANY PROPERLY DEFINED MARKET

Unless plaintiffs are able to demonstrate, in light of the undisputed facts, that Defendants possess "monopoly power" in a properly established relevant market, their claims under the Sherman Act fail. *Broadcom Corp.*, 501 F.3d at 306-07. The Supreme Court has defined "monopoly power" as the "power to control prices or exclude competition," and has long held

[81] *See also Yeager's Fuel, Inc. v. Pa. Power & Light Co.*, 953 F. Supp. 617, 645 (E.D. Pa. 1997) (noting that "the definition of a relevant market may be decided on summary judgment if the moving party satisfies Rule 56 requirements *and* 'shows its market theory describes the actual market behavior so accurately that the nonmoving party's assertion of the moving party's market power if not implausible, is at least unreasonable.'" (citation omitted)); *Huta v. Children's Hosp. of Philadelphia*, No. 93-2765, 1994 WL 245454, at *3 (E.D. Pa. 1994) (granting summary judgment where, among other deficiencies, plaintiffs' attempted product market definition was "impossible to evaluate"), *aff'd* 52 F.3d 315 (3d Cir. 1995); s*ee also Matsushita Elec. Indus. Co.*, 475 U.S. at 587.

that proof of such power under the antitrust laws requires reference to a properly defined antitrust product and geographic market. *United States v. E.I. DuPont de Nemours,* 351 U.S. at 391-94.

Third Circuit law instructs that the primary means of assessing monopoly power is through examination of defendants' market share. *See Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 201 (3d Cir. 1992) (monopoly power "may ordinarily be inferred from a predominant share of the relevant market") (quotation marks and citation omitted); *Weiss v. York Hosp.*, 745 F.2d 786, 827 (3d Cir. 1984) (stating that a "primary criterion used to assess the existence of monopoly power is the defendant's market share"). The Third Circuit's holdings comport with the widely accepted rule of thumb set forth by Judge Learned Hand: while ninety percent may be "enough to constitute a monopoly; it is doubtful whether sixty or sixty-four percent would be enough; and certainly, thirty-three percent is not." *United States v. Aluminum Co. of Am.,* 148 F.2d 416, 424 (2d Cir. 1945). Specifically, the Third Circuit has refused to find monopoly power where defendant's market share was less than 50%, and indeed has held that a market share of less than 55%, without other evidence tending to show monopoly power, "is insufficient *as a matter of law*" to establish that an antitrust defendant had monopoly power. *See Fineman,* 980 F.2d at 201(emphasis added); *see also Ideal Dairy Farms*, 90 F.3d at 749 (control of 47% of the market insufficient to show monopoly power). The market share thresholds are not appreciably different for Plaintiffs' attempted monopolization, conspiracy to monopolize, and Sherman Act § 1 claims.[82]

[82] *See, e.g., Barr Labs.,* 978 F.2d at 112-14, 115-16 (50% share insufficient for attempted monopolization claim); *Ramallo Bros. Printing v. El Dia, Inc.*, 392 F. Supp. 2d 118, 132 (D.P.R. 2005) ("A market share of less than 50 percent does not support a finding of dangerous probability of achieving a monopoly); *Acme Mkts. v. Wharton Hardware & Supply*, 890 F. Supp

(Continued . . .)

A. Undisputed Facts Demonstrate that TriCor Does Not Wield Monopoly Power in Either the Broader Market for Dyslipidemia Drugs or In Any Patient Treatment Category

The results of Dr. Gilbert's analysis demonstrate that TriCor does not possess monopoly power REDACTED

Gilbert Supp., ¶ 11 & Table 1a, DJA-1110, 1113. REDACTED

Id. REDACTED

Id. REDACTED

Id. REDACTED

Id.

Plaintiffs contend REDACTED

.[83] But the relevant issue for purposes of market definition and monopoly power

(. . . continued)
1230, 1241-42 (D.N.J. 1995) (40% market share insufficient for attempted monopolization); *Stewart Glass & Mirror, Inc. v. U.S.A. Glass, Inc.*, 940 F. Supp. 1026, 1037-38 (E.D. Tex. 1996) (recognizing 50% combined market share minimum for cognizable claim for conspiracy to monopolize); *Winter Hill Frozen Foods & Servs. v. Haagen-Dazs Co.*, 691 F. Supp. 539, 547-48 (D. Mass. 1988) (43% share insufficient in Section 1 case).

[83] Cockburn Rpt., ¶¶ 100-02, 131.1, DJA-709-11, 720-21; Schondelmeyer Rpt., ¶ 181, DJA-833-34; King Liab. Rebuttal, ¶ 37 n.51, DJA-1057.

is whether TriCor faces competition in all areas where it is prescribed, and as the undisputed facts demonstrate, REDACTED

[84]

REDACTED

Gilbert Supp., Table 2a, DJA-1114. REDACTED

Id. REDACTED

As discussed *supra*, Plaintiffs' experts frequently emphasize that REDACTED

Id. at Table 1a, DJA-1113. REDACTED

Id.

[84] Robins Dep., 152:12-13, DJA-88; Schwartzbard Dep., 364:14-366:4, DJA-147-48; Soto Dep., 165:2-7, DJA-189.

REDACTED

Gilbert Supp., ¶ 14-15 & Table 2a, DJA-1111, 1114. REDAC TED

.[86]

B. Plaintiffs' Only Proffered Empirical Analysis Similarly Demonstrates that TriCor Does Not Have Monopoly Power

Notwithstanding that Plaintiffs bear the burden of proving the relevant market, only one of Plaintiffs' experts, Iain Cockburn, conducted REDACTED

.[87] REDACTED

[85] *See* Cockburn Rebuttal, ¶ 61.5, DJA-1077-78 REDACTED

[86] Gilbert Supp., Table 2b, DJA-1114.

[87] No other expert even attempts an empirical analysis of TriCor market share.

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C. Plaintiffs' Attempts to Demonstrate Monopoly Power Through Direct Evidence Also Are Insufficient As a Matter of Law

Any effort by Plaintiffs to skirt the obstacles they face in defining a relevant market by demonstrating monopoly power through direct evidence also fails. The Third Circuit has

[88] Cockburn Rpt., ¶ 104, DJA-711-12.

[89] *Id.* at ¶¶ 106-07 & Ex. E, DJA-712-13, 730.

[90] *Id.* at Ex. F, DJA-731.

[91] *Id.*; Cockburn Dep., 91:14-17, DJA-106. REDACTED

Gilbert Rpt., ¶ 68, DJA-978-79.

acknowledged that "[t]he existence of monopoly power may be proven through direct evidence of supracompetitive prices and restricted output" or may "be inferred from the structure and composition of the relevant market." *Broadcom Corp.*, 501 F.3d at 304. Because, however, "'direct proof is only rarely available, courts more typically examine market structure in search of circumstantial evidence of monopoly power.'" *Harrison Aire, Inc. v. Aerostar Int'l, Inc.*, 423 F.3d 374, 381 (3d Cir. 2005) (quoting *U.S. v. Microsoft*, 253 F.3d 34, 51 (D.C. Cir. 2001)); *see also In re Remeron Direct Purchaser Antitrust Litig.*, 367 F. Supp. 2d 675, 680 n.7 (D.N.J. 2005) (noting that "although not explicitly forbidding a direct evidence approach, the Third Circuit has emphasized the important of establishing monopoly power by the traditional market definition approach.") (collecting cases). Plaintiffs in this case will not be able to offer any such direct proof.

1. There is No Evidence of Restricted Output.

Defendants' expert opines REDACTED

[92] REDACTED

.[93] All parties thus agree that REDACTED

There is therefore no evidence that defendants have restricted output of fenofibrate.

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[92] Guerin-Calvert Rpt, ¶ 72, DJA-1000.

[93] The most aggressive (and in some cases only) REDACTED Expert Report of Dr. Gregory Leonard ("Leonard Rpt."), ¶ 52, DJA-736 REDACTE ; Cockburn Rpt., ¶ 190, DJA-725 RED ACTE Leffler Rpt., ¶ 94, DJA-790-91 REDACTED Leitzinger Rpt., 70, DJA-768 REDACTED King Damages Decl., ¶ 40, DJA-817-18 REDACTE ; Singer Decl., ¶ 36, DJA-838-39 REDACTED

2. The "Evidence" of REDACTED to Demonstrate Monopoly Power

Plaintiffs refer repeatedly to the well-understood phenomenon that an AB-rated generic will enter the market at a price below that of its corresponding branded drug, and give great weight to their contention that REDACTED Aside from these unremarkable observations, which are insufficient to establish monopoly power, Plaintiffs offer no evidence that the price of TriCor is now, or ever has been, "supracompetitive."

Evidence that one competitor's product is more expensive than others "alone does not support a reasonable inference of monopoly power." *Harrison Aire,* 423 F.3d at 381. In a case that similarly involved allegations of delayed generic entry, the United States District Court for the District of New Jersey noted that accepting as evidence of supracompetitive pricing the fact that the AB-rated generic will enter at a price lower than that of the brand, "if applied beyond this case, would render most brand name pharmaceutical companies as *per se* monopolists prior to generic entry." *In re Remeron*, 367 F. Supp. 2d at 683 (emphasis in original); *cf. Ill. Tool Works,* 547 U.S. at 43 (explaining that it is not proper to presume market power from the existence of a patent, rather, such a conclusion "must be supported by proof of power in the relevant market."). A showing of supracompetitive pricing and monopoly power therefore requires "more proof than just a showing that a brand name drug costs more than a generic equivalent." *In re Remeron*, 367 F. Supp. 2d at 683.

Similarly, a number of Plaintiffs' economist experts suggest that REDACTED

[94] Such a position,

[94] Cockburn Rpt., ¶ 128, DJA-719 REDACTED ; Leitzinger Rpt., 45-52, DJA-756-63 REDACTED

(Continued . . .)

REDACTED

.[95] REDACTED

Like the plaintiffs in *Remeron*, Plaintiffs here "provide no evidence of excessive price-cost margins . . . but merely rely on the fact that later generic manufacturers could enter the market more cheaply than Remeron's price in order to establish monopoly power." *Id.* at 682.

CONCLUSION

For the reasons set forth above, the Court should grant Defendants' motion for summary judgment and dismiss Plaintiffs' federal and state law claims.

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Leffler Rpt., ¶ 22, DJA-780-81 REDACTED

[95] *In re Remeron*, 367 F. Supp. 2d at 683 ("Defendant here is a brand name (not generic) manufacturer whose initial fixed costs (including research, development, and the cost of being the first to gain FDA drug approval) are significantly higher than those of generic manufacturers because the Hatch-Waxman Act allows generic manufacturers to gain much of the benefit of a brand name manufacturers [sic] initial fixed costs by filing an ANDA.").

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Dated: May 5, 2008

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on May 13, 2008, the foregoing was caused to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to all registered participants.

In addition, the undersigned hereby certifies that true and correct copies of the foregoing were caused to be served via electronic mail on May 13, 2008 upon the following parties:

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